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| 10/080,053 | 02/21/2002 | Kenneth Houston | DR-332J | 6756 |

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| EXAMINER |
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BEISNER, WILLIAM H

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| ART UNIT | PAPER NUMBER |
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1744

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,053

Applicant(s)

HOUSTON ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-37 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 19-37 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 19, 22-33, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al.(Biosensors and Bioelectronics, Vol. 13).

With respect to claim 19, the reference of Park et al. discloses a culture vessel (f) that can hold culture medium and a sample. The vessel includes a bio-sensor having a coating (antibody) for attracting at least one pathogen (Salmonella). The device includes a detection circuit including an electrical connection between the bio-sensor and detection circuit for indicating the presence of pathogen on the bio-sensor (See Figure 1 and “2. Experimental” section). With respect to the claim limitation that the bio-sensor is sealed in the vessel, the reference of Park et al. discloses that the bio-sensor is held within a “dip holder with a plug”. This disclosure is interpreted to mean that the bio-sensor is held within the vessel in a sealed manner provided by the plug sealing the top opening of the vessel.

With respect to claims 22, 24-33 and 35, the disclosed detection electronics are capable of driving the bio-sensor over a range of frequencies (resonant frequency which varies as pathogens bind to the surface of the bio-sensor) and are capable of detecting shifts in the frequency over time (See the “Experiment” and “Results and discussion” sections). As shown in

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Figures 3-5, the detection circuit is configured to “continuously” and “instantaneously” detect a shift in frequency due to the attached pathogen.

With respect to claim 23, the detection circuit is external to the vessel (See Figure 1).

With respect to claim 33, the system would inherently include electric wire for the electrical connection as is required for connecting the bio-sensor electrodes to the driving and sensing components shown in Figure 1.

With respect to claim 36, the seal or plug is provided at the top of the vessel.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (Biosensors and Bioelectronics, Vol. 13).

The reference of Park et al. has been discussed above.

Claim 34 differs by specifically reciting that the electrical connection between the bio-sensor and detection circuit uses a cable.

The use of cables for providing the electrical connection of a plurality of wires between two electronic components is notoriously well known in the art.

As a result, it would have clearly been within the purview one having ordinary skill in the art to provide the electrical wires connecting the bio-sensor to the oscillator and analyzer in a cable format for the known and expected results of facilitating the connection of the bio-sensor to the detection circuitry.

7. With respect to claim 37, while the reference of Park et al. discloses that the sensor is communicated within the vessel through the top, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to communicate the sensor through a side or bottom of the vessel while still providing the required function of communicating the biosensor with the interior of the vessel while

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maintaining the vessel in a sealed condition. Note mere rearrangement of parts is not a patentable distinction (See *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950))

8. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (Biosensors and Bioelectronics, Vol. 13) in view of Karube et al. (EP 0 215 669).

The reference of Park et al. has been discussed above.

Claims 20 and 21 differ by reciting that the biosensor for pathogen detection includes an array of biosensor elements with different coatings for attracting pathogens.

The reference of Karube et al. discloses that it is known in the art to provide an array of biosensor elements with respect to a single sensor device so as to simultaneously analyze a plurality of different analytes or pathogens (See page 7, lines 4-11, and Figure 16).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference so as to include an array of biosensor elements as suggested by the reference of Karube et al. for the known and expected result of providing a means recognized in the art for detecting a plurality of pathogens within a single sample.

9. Claims 19 and 22-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (Biosensors and Bioelectronics, Vol. 13) in view of Qu et al. (Analytica Chimica) or He et al. (Talanta).

With respect to claim 19, the reference of Park et al. discloses a culture vessel (f) that can hold culture medium and a sample. The vessel includes a bio-sensor having a coating (antibody)

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for attracting at least one pathogen (Salmonella). The device includes a detection circuit including an electrical connection between the bio-sensor and detection circuit for indicating the presence of pathogen on the bio-sensor (See Figure 1 and “2. Experimental” section). With respect to the claim limitation that the bio-sensor is sealed in the vessel, the reference of Park et al. discloses that the bio-sensor is held within a “dip holder with a plug”. This disclosure is interpreted to mean that the bio-sensor is held within the vessel in a sealed manner provided by the plug sealing the top opening of the vessel.

If the disclosure is interpreted that the recited plug is an electrical plug and does not seal the vessel, the references of Qu et al. and He et al. are cited as prior art that discloses communicating a quartz crystal sensor within a culture vessel wherein a seal is provided between the vessel and an electrical connection (See Figure 1 of Qu et al. and Figure 1 of He et al.).

In view of either of these disclosures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to communicate the biosensor of the device of the primary reference using a vessel and sensor configuration of either of the references of Qu et al. or He et al. for the known and expected result for providing a means recognized in the art for communicating a quartz crystal sensor with the liquid contents of a culture vessel while protecting the contents of the vessel from contamination from the surrounding environment which is known in the art for ensuring the integrity of the test system.

With respect to claims 22, 24-33 and 35, the disclosed detection electronics are capable of driving the bio-sensor over a range of frequencies (resonant frequency which varies as pathogens bind to the surface of the bio-sensor) and are capable of detecting shifts in the frequency over time (See the “Experiment” and “Results and discussion” sections). As shown in

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Figures 3-5, the detection circuit is configured to “continuously” and “instantaneously” detect a shift in frequency due to the attached pathogen.

With respect to claim 23, the detection circuit is external to the vessel (See Figure 1).

With respect to claim 33, the system would inherently include electric wire for the electrical connection as is required for connecting the bio-sensor electrodes to the driving and sensing components shown in Figure 1.

With respect to claim 36, the seal or plug is provided at the top of the vessel.

Claim 34 differs by specifically reciting that the electrical connection between the bio-sensor and detection circuit uses a cable.

The use of cables for providing the electrical connection of a plurality of wires between two electronic components is notoriously well known in the art.

As a result, it would have clearly been within the purview one having ordinary skill in the art to provide the electrical wires connecting the bio-sensor to the oscillator and analyzer in a cable format for the known and expected results of facilitating the connection of the bio-sensor to the detection circuitry.

With respect to claim 37, while the reference of Park et al. discloses that the sensor is communicated within the vessel through the top, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to communicate the sensor through a side or bottom of the vessel while still providing the required function of communicating the biosensor with the interior of the vessel while maintaining the vessel in a sealed condition. Note mere rearrangement of parts is not a patentable distinction (See *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950))

10. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al.(Biosensors and Bioelectronics, Vol. 13) in view of Qu et al.(Analyticaa Chimica) or He et al.(Talanta) taken further in view Karube et al.(EP 0 215 669).

The reference of Park et al. has been discussed above.

Claims 20 and 21 differ by reciting that the biosensor for pathogen detection includes an array of biosensor elements with different coatings for attracting pathogens.

The reference of Karube et al. discloses that it is known in the art to provide an array of biosensor elements with respect to a single sensor device so as to simultaneously analyze a plurality of different analytes or pathogens (See page 7, lines 4-11, and Figure 16).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference so as to include an array of biosensor elements as suggested by the reference of Karube et al. for the known and expected result of providing an means recognized in the art for detecting a plurality of pathogens within a single sample.

Response to Arguments

11. Applicant's arguments filed 2/3/05 have been fully considered but they are not persuasive.

12. With respect to the rejection of the claims under 35 USC 102 over the reference of Park et al., Applicants argue (See pages 7-9 of the response filed 2/3/05) that the “plug” of Park is an

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electrical connector and not a seal for the vessel. Applicants' conclusion is based on the disclosure of the process of "dipping" the implies momentary or partial immersion.

In response, it is not clear how Applicants can positively conclude that the reference to a "plug" is an electrical connector. The disclosure is silent as to "plugging" the connector to the driving monitoring system. Applicants' discussion of "dipping" does not preclude the use of a plug that holds the sensor and dips the sensor within the vessel while also sealing the vessel from contamination during use. Even if the sensor can be reused, the sensor is maintained in contact with the interior of the culture vessel during the detection method.

13. With respect to the rejection of the claims over the combination of the references of Park et al. and Karube et al., Applicants argue (See page 9 of the response dated 2/3/05) that dependent claims 20 and 21 are patentable in view of the patentability of claim 19.

In response, the Examiner is of the position that claim 19 is not patentable for the reasons set forth with respect to the rejection of the claims over the reference of Park et al. alone or further in view of Qu et al. or He et al.

14. With respect to Applicants' comments concerning the reference of Hu et al. (See pages 9-11 of the response dated 2/3/05), the Examiner is of the position that while the method performed by the reference of Hu et al. is different, the reference is pertinent in view of the fact that the reference discloses that it is conventional in the art to provide a culture vessel in a sealed condition while contacting a quartz crystal sensor within the contents of the vessel during a detection method.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

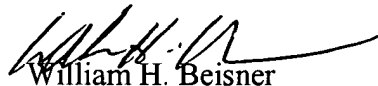
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB